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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,470	11/02/2005	Roger R. Dzwonczyk	OSU2949PCTUS	4111

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EXAMINER	
STOUT, MICHAEL C	
ART UNIT	PAPER NUMBER
4123	

NOTIFICATION DATE	DELIVERY MODE
01/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/555,470	DZWONCZYK ET AL.	
	Examiner	Art Unit	
	MICHAEL C. STOUT	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *3-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 and 2, drawn to detecting ischemia.

Group 2, claim(s) 1, 3 and 4, drawn to detecting stenosis.

Group 3, claim(s) 1, 5 and 6, drawn to detecting the extent of reperfusion.

Group 4, claim(s) 1 and 7, drawn to detecting tissue rejection following heart transplant.

Group 5, claim(s) 1 and 8, drawn to detecting the effectiveness of cardioplegia.

Group 6, claim(s) 1 and 9, drawn to detecting effectiveness of ischemia preconditioning.

2. The inventions listed as Groups 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1 is drawn to a method for measuring a physiological state of the myocardium comprising attaching electrodes and recording a computing various measurements of a baseline impedance value, periodically measuring impedance and using the measurements to diagnosis a myocardial physiologic state as a smooth continuous function. All the elements of which are known in the prior art.

There is a clear lack of unity of the invention because the common matter of the independent claims is well known and the remaining subject matter of each clam differs from that of the others without there being any unifying novel inventive concept.

3. Claims 1 link(s) Groups I-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the liking claim(s) 1. Upon the indication of allowability of the liking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitation of the allowable liking claim(s) will be rejoined and fully examined for patentability. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is present prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by or includes all the limitation of the allowable liking, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn. The provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler,* 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971).

4. During a telephone conversation with Frank Foster on January 11, 2008 a provisional election was made without traverse to prosecute the invention of Group 1, claims 1 and 2. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The disclosure is objected to because of the following informalities: On Page 13, Line 19 of the disclosure there is a comma in the phrase "mean, baseline" which should read the "sum of the mean baseline myocardial impedance..." the comma should be removed.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Howie et al. ("*An Evaluation of a New Two-Electrode Myocardial Electrical Impedance Monitor for Detecting Myocardial Ischemia*", Anesth Analg 2001, 92:12-8) as evidenced by Dzwonczyk et al. (US 5,454,377) in view of Moskowitz (US 5,767,117).

Howie discloses a method for detecting a quantitative measure of a physiologic state of a dog myocardium or coronary artery (it would be obvious to modify a method tested in animals which shows great promise of detecting myocardial damage, cardiac rejection, and CABG surgery, see Page 17, Column 2, Last Paragraph, to detect a physiological state of a human because initial medical investigation in animals is

notoriously well known to be used initially to develop treatment methods and techniques to be used in humans), the method comprising:

a) attaching at least one electrode pair to the myocardium (a pair of ventricular pacing leads were placed into heart tissue, see Page 14, Column 1, Paragraph 3);

b) recording baseline measurements of the mean myocardial electrical impedance (comparison between baseline values for each study group was performed, see Table 1, and Page 15, Column 1, Paragraph 2) and computing the variance of the myocardial electrical impedance between each electrode pair (Table 1 shows a calculated variance of the myocardial impedance);

c) computing a baseline value of mean myocardial electrical impedance from the baseline measurements (the calculated average baseline values are shown in Table 1) ;

d) periodically measuring mean myocardial electrical impedance values between each electrode pair over an interval of time (MEI measurements were made every 4 minutes, see Page 13, Column 1, Paragraph 2) and storing data representing the impedance values as a function of time (Howie discloses a MEI measurement device described by Dzwonczyk in US 5,454,377, see Howie Page 13, Column 1, Paragraph 4,in which the microcontroller performs all the measuring function and returns the results to the PC via a serial connection, (see Howie Page 13, Column 1, Paragraph 5) where all data is stored in an unreduced format for subsequent analysis, see Dzwonczyk Column 4, Lines 40-47) ; and

e) after the mean myocardial electrical impedance changes from the computed baseline value by at least the measured variance (Howie Figures 2 and 3 show the

mean myocardial impedance values changing from the baseline by at least the measured variance), diagnosing the extent of change in the myocardial physiologic state as a function of the extent of change, or rate of change, of the periodically measured myocardial electrical impedance from the baseline value (Figure 2 shows the extent of ischemia as a function of the percent change from the baseline and Figure 3 shows the extent of ischemia as a function of the extent of change).

Howie fails to disclose a method for detecting a quantitative measure of a physiologic state of a human, wherein the extent of change is diagnosed as a continuous smooth function.

Moskowitz teaches a method of creating a continuous smooth function by taking a non-continuous and smooth data plot and using curve fitting to approximate the graph data.

Both Howie and Moskowitz both teach plotting and analyzing data. Thus it would have been obvious to a person of ordinary skill in the art to modify the method disclosed by Howie by creating a continuous smooth function to approximate the raw data as taught by Moskowitz in order to provide curve continuous smooth curve fitting the data which provides a mathematical function which can be used to create a relationship of the recorded data.

Regarding Claim 2 Howie in view of Moskowitz teaches the method of claim 1 as set forth above, wherein

a) the physiologic state is the extent of ischemia of a portion of the myocardium (Howie Figures 2 and 3 show MEI resulting in a change in the extend of ischemia); and

b) after the mean myocardial electrical impedance between the electrode pairs rises above a value equal to the arithmetic sum of the baseline myocardial electrical impedance and the variance (Howie Figures 2 and 3 show the mean myocardial impedance values changing from the baseline by at least the measured variance), myocardial ischemia severity is diagnosed as a continuous, smooth, increasing function of the extent of the rise of the mean myocardial electrical impedance above the baseline value (Howie Figures 2 and 3 both shows ischemia resulting in an increasing function which rises above the baseline mean and variance).

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. "Use of Myocardial Electrical Impedance to Assess the Efficacy of Preconditioning," CL del Rio et al. Computers in Cardiology 2002; 29:489-492.

b. “Myocardial Electrical Impedance Response to Ischemia and Reperfusion in Humans,” R Dzwonczyk et al. Computers in Cardiology 2002; 29:541-543.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is

(571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCS

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4123